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Tierney  
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David Tierney, M.D.  
Senior Vice President Medical & Regulatory Affairs,  
Roberts Pharmaceutical Corporation  
4 Industrial Way West  
Eatontown, NJ 07724

Re: Meeting on

Dear Dr. Tierney:

I am writing to thank you for the productive meeting we had on

I would also like to thank Mr. A. Howard, Dr. M. Kabadi, and Dr. Haenick for providing me detailed and accurate information. I think that we are forging a strong co-development team that will take Emitasol® to US and EU approval in as short a time as possible.

I understand the problems that led to the reformulation of Emitasol® and the development of a stability-indicating assay. I do hope that we conclude the reformulation process as well as the assay development and validation efforts within the current timeline. A. Howard and I have agreed that certain toxicology and possibly animal bioavailability work is necessary prior to communicating with CDER on this issue. Your new resident toxicologist will certainly have input on the framework that we agreed on. A comparative toxicology work will allow us to bridge the safety information of the old formula with the new one and will help us in avoiding any potential clinical hold.

A number of issues regarding the statistical assumptions/sample size of the diabetic gastroparesis protocol remain to be discussed and decided upon. Dr. Haenick is organizing a teleconference to discuss and resolve these issues.

As discussed during our meeting, RiboGene is proceeding with the EU registration of Emitasol® and with the planning of an appropriately powered Phase III study to determine the efficacy and safety of intranasal metoclopramide in chemotherapy-induced delayed-onset emesis. We will be performing this study most likely in the UK. Your proposal to

and assist us with the manufacturing of the test agent and placebo will certainly accelerate the commencement and completion of this study. I plan to have a draft protocol before and, depending on the particular demands of UK

